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INTELLECTUAL PROPERTY DEPARTMENT			GULLEDGE, BRIAN M	
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/527,071	ANTHONY ET AL.			
Office Action Summary	Examiner	Art Unit			
	Brian Gulledge	1619			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	l. lely filed the mailing date of this communication. (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>08 Oct</u> This action is <b>FINAL</b> . 2b)⊠ This     Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 96-151 is/are pending in the application 4a) Of the above claim(s) 102-106,111,112,125 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 96-101,107-110,113-124,127-136 and 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	5 <u>,126 and 137-147</u> is/are withdrav <u>d 148-151</u> is/are rejected.	vn from consideration.			
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examine 11.	epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 10/6/08.	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	te			

#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election of Group II (method of treating keratinous material) and species for the active material ("a" in newly added claim 101) and the carrier agent (polymers derived from ethylenically unsaturated monomers) in the reply filed on October 8, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 102-106, 111-112, 125-126, and 137-147 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

#### **Priority**

This application claims benefit to provisional application No. 60/409,352, filed on September 9, 2002, in a language other than English. An English translation of the non-English language provisional application and a statement that the translation is accurate must be filed in provisional application No. 60/409,352. See 37 CFR 1.78(a)(5). The English translation and a statement that the translation is accurate required by 37 CFR 1.78(a)(5) is missing. Accordingly, applicant must supply 1) the missing English translation and a statement that the translation is accurate in provisional application No. 60/409,352 and 2) in the present application, a confirmation that the translation and statement were filed in the provisional application. If 1)

and 2) are not filed (or the benefit claim withdrawn by the filing of an amendment or Supplemental Application Data Sheet) prior to the expiration of the time period set in this Office action, the present application will be abandoned. See 37 CFR 1.78(a)(5)(iv).

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 96-101, 107-110, 113-124, 127-130, and 148-151 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "carrier agent" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See *Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See *Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful carrier agents generally, a potentially huge genus inclusive of many different polymers having widely divergent structures and functions. The specification discloses properties that the carrier

agent may (but does not necessarily) possess (page 27, line 17 – page 29, line 23), as well as numerous monomers which may be a part of the polymer (pages 29-45). However, the specification discloses only a limited number of species (five) of the instantly recited polymeric carrier agent (as opposed to potential monomers that may be present) at page 34, lines 8-27, and these are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 96-101, 107-110, 113-124, 127-136, and 148-151 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "active material" in claims 96 and 98 is equivalent to claiming an effective amount, but the claim does not specify for what the active ingredient is effective. The phrase "an effective amount" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. *In re Fredericksen* 213 F.2d 547, 102 USPQ 35 (CCPA 1954).

Claims 97, 113, and 117 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 97 recites that the active material comprises a

compound different form the active material. It is unclear how the "active material" is to be different from itself.

Claim 98 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 98 recites the limitation "a method for improving the deposition of an active material onto keratinous material". There is insufficient antecedent basis for this limitation in the claim, as the claim does not recite a point of comparison for which the instantly recited method is improvement thereupon.

Claim 114 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. *See Honeywell Intl. v. Intl. Trade Commn.*, 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it). Accordingly, the zeta potential values recited by instant claim 114 are incomplete insofar as it does not specify the frame of reference used to measure them, e.g., the pH of the sample. A zeta potential value on its own without defining the solution conditions is a virtually meaningless number.

Application/Control Number: 10/527,071 Page 7

Art Unit: 1619

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 96-101, 107-110, 113-115, 117-121, 124, 127-130, and 148-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (PCT Patent Application Publication WO 97/09030; published March 13, 1997). Schwartz et al. discloses shampoo compositions comprising latex polymer particles, wherein the shampoo has a good deposition profile without requiring organic solvents (page 1, line 29 – page 2, line 11). The composition disclosed includes latex polymers with a glass transition temperature between about -20 °C and about 10 °C, compatible surfactants, an aqueous carrier, and optional material (page 2, lines 14-19). The optional material includes a cationic polymer for use to aid deposition of the latex polymer (page 9, lines 34-36 and examples I-IX). Schwartz et al. also discloses the method of using the shampoo composition, which includes applying the shampoo to hair (a keratinic material) and rinsing (page 14, lines 18-20), with the latex material being left behind on the hair after rinsing (page 17, lines 3-19). Thus, Schwartz et al. discloses all of the limitations recited in instant claim 96 except for the limitation that the formulation has a pH between 3 and 5.5. Schwartz et al. does not disclose the pH for any of the specific examples discloses, and states only that the pH will be from about 4 to about 8 (page 10, lines 25-27). This range overlaps the instantly recited range, and in cases involving overlapping ranges, the courts have consistently

held that even a slight overlap in range establishes a *prima facie* case of obviousness. *In re Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Schwartz et al. discloses that the tested examples have better style hold performance than the control formulation (page 17, table 3), and as such this disclosure reads on instant claim 98.

Schwartz et al. discloses compositions with 4 wt% of the latex (per approximately 100 mL of solution) (page 15, examples I, II, and IV), which translates to about 0.4 g/L, a value that reads on the range recited in instant claim 99. Instant claim 100 recites that the pH of the aqueous rinsing medium is from 5.5 to 8, and while Schwartz et al. does not disclose the pH of the water used to rinse the hair (page 17, lines 5-6), the pH of both tap water and deionized water read on the instantly recited range.

The latex polymer used in the shampoo disclosed by Schwartz et al. includes several methyl methacrylate/butyl acrylate/ammonium methacrylate/allyl methacrylate copolymers (Syntran EX26-2, -5, -9, and -13; pages 15-16, examples I, II, IV, VII, and IX). These latex polymers read on the limitations to the active material recited in instant claims 101 and 108-110. Schwartz et al. discloses that the latex particles are dispersed in the composition (primarily by the surfactant) and the particles have an average diameter from about 0.05 μm to about 0.5 μm (page 3, lines 10-17). This disclosure teaches the limitations recited in instant claim 107.

Instant claims 115 and 151 recite the inclusion of an additional ingredient, such as a fragrance, and Schwartz et al. discloses the inclusion of a perfume in the shampoo compositions (page 15, examples I-V). Schwartz et al. discloses the use of the cationic surfactant cocamidopropyl betaine in 4.3 wt% (page 15, example II), reading on the ranges recited in

instant claims 118 and 119. The same composition comprises 84 wt% water and 0.6 wt% alcohol, reading on the limitations recited in instant claims 120 and 121.

Instant claims 124 and 127-130 further limit the carrier agent composition. Schwartz et al. discloses the use of cationic polymers in the composition, and this polymer can be Merquat 550, a copolymer of acrylamide and dimethyl diallylammonium chloride with a molecular weight of 160,000 g/mol (page 12, lines 6-8). This polymer can be present in 0.3 to 0.7 wt% of the formulation (page 15, examples I-V), reading on the range recited in instant claim 148. Instant claim 149 recites the inclusion of a salt, and this is read on by the disclosed inclusion of salts such as sodium chloride (page 13, line 7) in from 0.01 to 10 wt% (page 13, lines 36-37). The above discussed amounts also overlap the ranges recited in instant claim 150.

Claim 116 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (PCT Patent Application Publication WO 97/09030; published March 13, 1997) as applied to claim 115 above, and further in view of Cauwet et al. (US Patent 5,798,121; issued August 25, 1998). Schwartz et al. discloses a shampoo composition for use to clean and style hair, but does not disclose the inclusion of silicone oil, as recited in instant claim 116.

Cauwet et al. discloses a composition for treating hair that comprises a conditioner (column 3, lines 44-53). The conditioner can be silicone oil (column 3, line 50 and column 4, example I).

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose (treating and styling hair), in order to form a third composition to be used for the very same purpose (a combination shampoo and conditioner). The

idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

Claims 122-123 and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (PCT Patent Application Publication WO 97/09030; published March 13, 1997) as applied to claim 96 above, and further in view of Sterling (US Patent 4,075,131; issued February 21, 1978). Schwartz et al. teaches all of the limitations of instant claims 122, 123, and 136 except for the inclusion of the recited species of polymer.

Sterling discloses a conditioning shampoo used to clean and condition hair (abstract). The composition disclosed includes a zwitterionic polymer (column 6, examples 1 and 2) that is a copolymer of beta-dimethylaminoethyl methacrylate and acrylic acid, followed by treatment with ammonium persulfate (column 5, line 59 – column 6, line 9). The pH of this composition is from 5.8 to 6.5 (column 6, lines 36-37).

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose (shampoos to treating hair), in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

Claims 131-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (PCT Patent Application Publication WO 97/09030; published March 13, 1997) as applied to claim 96 above, and further in view of Matz et al. (PCT Patent Application Publication WO 01/05365; published January 25, 2001). Schwartz et al. teaches

all of the limitations of instant claims 131-135 except for the inclusion of the recited species of polymer.

Matz et al. discloses polymers useful in treating keratin material (page 1, lines 5-13). The disclosed polymer can be incorporated into shampoos (page 2, lines 19-32). These polymers are made by copolymerizing a first monomer, which can be either methacrylamidopropyltrimethyl ammonium halide (MAPTAC) or dimethyl diallyl ammonium halide (DADMAC) with acrylic or methacrylic acid, and optionally with a C<sub>1</sub>-C<sub>3</sub> alkyl acrylate (page 11, line 20 – page 12, line 8). The resultant polymer has a molecular weight of at least 10,000 g/mol (page 12, lines 8-10).

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose (shampoos to treating hair), in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/527,071 Page 12

Art Unit: 1619

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**BMG** 

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612